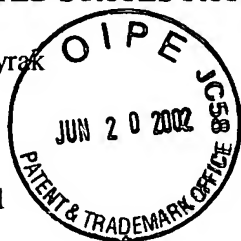


PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Albayrak



Atty Docket No.: 0081.01

Examiner: Unknown

Application No. 10/027,401

Group Art Unit: Unassigned

Filed: 12/19/01

Title: INDUCED PHASE TRANSITION
METHOD FOR THE PRODUCTION
OF MICROPARTICLES CONTAINING
HYDROPHOBIC ACTIVE AGENTS

CERTIFICATE OF MAILING

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Signed: Kathy Honnert

INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §1.56, §1.97 and §1.98

Commissioner for Patents
Washington, DC 20231

Dear Sir:

The references listed in the attached PTO Form 08A and 08B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

Copies of the references are enclosed, as required under 37 CFR §§1.98. The references on the attached Form 1449 identified by an asterisk (*) were previously cited by or submitted to the PTO in a prior application relied upon for an earlier filing date. Accordingly, in compliance with 37 CFR §§1.98 (d), copies of these references have not been provided.

Attorney Docket No. 0081.01

This Information Disclosure Statement is being timely filed under 37 CFR §1.97 and is being filed:

- ☒ within three months of the filing date of a national application; within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or before the mailing date of a first Office action on the merits (whichever event occurs last);
- ☐ more than three months from the filing date of an application and after the mailing date of a first Office action on the merits, but before the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311 (whichever occurs first), and is accompanied by:
- ☐ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under §1.97(c) (\$180.00); or
 - ☐ one of the following statements as specified in 37 CFR 1.97(e) that:
 - ☐ each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in section 1.56(c) more than three months prior to the filing of the information disclosure statement; or
- ☐ after the mailing date of either a final action under section 1.113 or a notice of allowance under section 1.311, but on or before the payment of the issue fee, and is accompanied by each of:
- ☐ the following petition:

Applicant hereby requests consideration of the accompanying information disclosure statement;
 - ☐ the petition fee set forth in 37 CFR 1.17(i) (\$130.00); and
 - ☐ one of the following statements as specified in 37 CFR 1.97(e) that:
 - ☐ each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three

months prior to the filing of the information disclosure statement; or

☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in section 1.56(c) more than three months prior to the filing of the information disclosure statement.

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Respectfully submitted,

INHALE THERAPEUTIC, INC.

Dated: 3/25/02

By:


Michael J. Rafa
Reg. No. 38,740

San Carlos, CA 94070
(650) 631-3100



Practitioner's Docket No. 0081.01

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Albayrak, Celal

Application No.: 10/027,401

Group No.: Unknown

Filed: December 19, 2001

Examiner: Unknown

For: INDUCED PHASE TRANSITION METHOD FOR THE PRODUCTION OF
MICROPARTICLES CONTAINING HYDROPHOBIC ACTIVE AGENT

Assistant Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
WITHIN THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING
INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

Date: 3/25/02

Michael J. Rafa
Signature of Practitioner

Reg. No.: 38,740
Tel. No.: 650-631-5053
Customer No.: 21968

Michael J. Rafa
Inhale Therapeutic Systems, Inc.
150 Industrial Road
San Carlos, CA 94070
U.S.A.

CERTIFICATION UNDER 37 C.F.R. ' ' 1.8(a) and 1.10*

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Kathy Honnert
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Kathy Honnert
(type or print name of person certifying)



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO			Complete if Known		
			Application Number	10/027.401	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Filing Date	12/19/01	
			First Named Inventor	Celal Albayrak	
			Art Unit		
			Examiner Name		
Sheet	1	of	4	Attorney Docket Number	0081.01

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	AA	US- 3523906	08/11/1970	Vrancken et al.	
	AB	US- 3691090	09/12/1972	Kitajima et al.	
	AC	US- 3737337	06/05/1973	Schnoring et al.	
	AD	US- 3891570	06/24/1975	Fukushim et al.	
	AE	US- 3943063	03/09/1976	Morishita et al.	
	AF	US- 3960757	06/01/1976	Morishita et al.	
	AG	US- 4166800	09/04/1979	Fong	
	AH	US- 4384975	05/24/1983	Jones W. Fong	
	AI	US- 4389330	06/21/1983	Tice et al.	
	AJ	US- 4568559	02/04/1986	Nuwayser et al.	
	AK	US- 4652441	03/24/1987	Okada et al.	
	AL	US- 4675189	06/23/1987	Kent et al.	
	AN	US- 4732763	03/22/1988	Beck et al.	
	AO	US- 4835139	05/30/1989	Tice et al.	
	AP	US- 4897268	01/30/1990	Tice et al.	
	AQ	US- 4917893	04/17/1990	Okada et al.	
	AR	US- 4954298	09/04/1990	Yamamoto et al.	
	AS	US- 4962091	10/09/1990	Eppstein et al.	
	AT	US- 4994281	02/19/1991	Muranishi et al.	
	AU	US- 5019400	05/28/1991	Gombotz et al.	

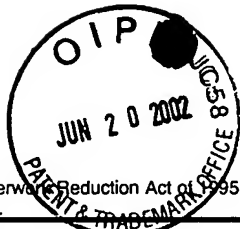
FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	-Number ⁴ -Kind Code ⁵ (if known)				
	CW	EP	04481732	03/01/1995	Takeda Chemical		
	CX	EP	0668073	04/14/1999	Takeda Chemical		
	CY	EP	202065	05/06/1986	Takeda Chemical		
	CZ	EP	251476	05/22/1986	Syntex		
	DA	EP	302582	03/31/1987	Southern Research		
	DB	EP	330180	02/22/1989	BioMaterials Univ.		
	DC	EP	190833	08/13/1986	Takeda Chemical		
	DD	EP	0315875	05/17/1989	Hoechst		
	DE	EP	438426	09/13/1989	DuPont		
	DF	EP	582459	08/03/1993	Takeda Chemical		

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 2 of 4			Complete if Known	
			Applicant Number	10/027.401
			Filing Date	12/19/01
			First Named Inventor	Celal Albayrak
			Art Unit	
			Examiner Name	
			Attorney Docket Number	0081.01

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	AV	US-5271961	12/12/1993	Mathiowitz et al.	
	AW	US-5330767	07/19/1994	Yamamoto et al.	
	AX	US-5366734	11/22/1994	Hutchinson et al.	
	AY	US-5384133	01/24/1995	Boyes et al.	
	AZ	US-5445832	08/29/1995	Orsolini et al.	
	BA	US-5500161	03/19/1996	Andrianov et al.	
	BB	US-5503851	04/02/1996	Mank et al.	
	BC	US-5536508	07/16/1996	Canal et al.	
	BD	US-5556642	09/17/1996	Kobayashi et al.	
	BE	US-5594091	01/14/1997	Igari et al.	
	BF	US-5603960	02/18/1997	O'Hagen et al.	
	BG	US-5609886	03/11/1997	Wantier et al.	
	BH	US-5611971	03/18/1997	Maedera et al.	
	BI	US-5622657	04/22/1997	Takada et al.	
	BJ	US-5631020	05/20/1997	Okada et al.	
	BK	US-5631021	05/20/1997	Okada et al.	
	BL	US-5635216	06/03/1997	Thompson	
	BM	US-5643605	07/01/1997	Cleland et al.	
	BN	US-5648095	07/15/1997	Illum et al.	
	BO	US-5648096	07/15/1997	Gander et al.	

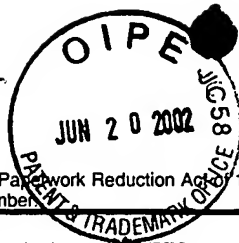
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³	Number ⁴ - Kind Code ⁵ (if known)			
	DG	EP	580428	07/22/1993	Takeda Chemical	
	DH	EP	797615	03/27/1995	Univ. of Nottingham	
	DI	CA	2100925			
	DJ	CA	2009941			
	DK	GB	1405108	12/23/1971	Agfa-Gevaert	
	DL	UK	2234896			
	DM	WO	90/13780	11/15/1990	Enzytech Inc.	
	DN	WO	97/19676	06/05/1997	Schering	
	DO	WO	98/07442	02/26/1998	Intl Ctr Genetic	
	DP	WO	98/27962	07/02/1998	Alza Corp.	

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/027.401	
			Filing Date	12/19/2001	
			First Named Inventor	Celal Albayrak	
			Art Unit		
			Examiner Name		
Sheet	3	of	4	Attorney Docket Number	0081.01

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	BP	US-5650173	07/22/1997	Ramstack et al.	
	BQ	US-5661125	08/26/1997	Strickland	
	BR	US-5676968	10/14/1997	Lipp et al.	
	BS	US-5700486	12/23/1997	Canal et al.	
	BT	US-5723269	03/03/1998	Akagi et al.	
	BU	US-5733567	03/31/1998	Arola et al.	
	BV	US-5783567	07/21/1998	Hedley et al.	
	BW	US-5766637	06/16/1998	Shine et al.	
	BX	US-5792477	08/11/1998	Rickey et al.	
	BY	US-5849884	12/15/1998	Woiszwilllo et al.	
	BZ	US-5851451	12/22/1998	Takechi et al.	
	CA	US-5853698	12/29/1998	Straub et al.	
	CB	US-5863554	01/26/1999	Illhun et al.	
	CC	US-5902565	05/11/1999	Cox et al.	
	CD	US-5902834	05/11/1999	Porrvik et al.	
	CE	US-5916598	06/29/1999	Rickey et al.	
	CF	US-5922357	07/13/1999	Coombes et al.	
	CG	US-5929196	07/27/1999	Kissel et al.	
	CH	US-5955143	09/21/1999	Wheatley et al.	
	CI	US-5980947	11/09/1999	Yamakawa et al.	

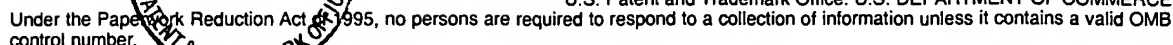
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³	Number ⁴ - Kind Code ⁵ (if known)			
	DQ	WO	99/20253	04/29/1999	Bioglan Thera.	
	DR	WO	99/29304	06/17/1999	MA Inst. of Tech	
	DS	WO	99/58112	11/18/1999	Microbiological	
	DT	WO	00/04916	07/09/1999	Biomeasure Inc.	
	DU	WO	99/59548	11/25/1999	Mogam	
	DV	WO	01/28591	04/26/2001	Genentech	

Examiner Signature		Date Considered	
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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	10/027,401
Filing Date	12/19/01
First Named Inventor	Celal Albayrak
Group Art Unit	
Examiner Name	
Attorney Docket Number	0081.01

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	DW	ARSHADY, "Preparation of biodegradable microspheres and microcapsules: 2. Polyactides and related polyesters," J. of Cont. Rel., 17th ed., p. 1-22, (February 5, 1991).	
	DX	WATTS ET AL., "Microencapsulation Using Emulsification/Solvent Evaporation: An Overview of Techniques and Applications," Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 7 (No. 3), p. 235-259, (February 5, 1990).	
	DY	WANG ET AL., "Preparation and Characterization of Poly(lactic-co-glycolic acid) Microspheres for Targeted Delivery of a Novel Anticancer Agent, Taxol," Chem. Pharm. Bull., Pharmaceutical Society of Japan, Vol. 44 (No. 10), p. 1935-1940, (October 1, 1996).	
	DZ	GHADERI ET AL., "Effect of preparative parameters on the characteristics of poly (D,L-lactide-co-glycolide) microspheres made by the double emulsion method," International Journal of Pharmaceutics, Elsevier Science B.V., p. 205-216, (June 16, 1996).	
	EA	CLELAND, "Solvent evaporation processes for the Production of Controlled Release Biodegradable Microsphere Formulations for Therapeutics and Vaccines," Biotechnol. Prog., 1st ed., American Chemical Society & American Institute of Chemical Engineers, Vol. 14 (No. 1), p. 102-107, (February 6, 1998).	
	EB	O'DONNELL ET AL., "Properties of multiphase microspheres of poly(dl-lactic acid) or poly(dl-lactic-co-glycolic acid) produced by mechanical agitation, sonication, or potentiometric dispersion," J. Microencapsulation, Taylor & Francis Ltd., Vol. 13 (No. 6), p. 667-677, (February 5, 1996).	
	EC	CARTI, "A new approach to improved stability and controlled release in double emulsions, by the use of graft-comb polymeric amphiphiles," Acta Polym, Wiley-VCH (Weinheim), p. 606-616, (February 5, 1998).	
	ED	AFTABROUSHAD ET AL., "Factors Influencing the Entrapment of a Water Soluble Model Drug into Injectable Microparticles Prepared Using Solvent Evaporation and Phase Separation Techniques," Eur. J. Pharm BioPharm, medpharm GmbH Scientific Publishers (Stuttgart), Vol. 40 (No. 4), p. 237-242, (February 5, 1994).	

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Signature

Date
Considered

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